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Tab 9

PREMARKET NOTIFICATION [510(k)] Summary

Trade Name: CTS-7700 with C3L60B and L7L38B Transducers

JUN - 6 2006

Common Name: Digital Ultrasound Imaging System

Classification Name: Ultrasonic Pulsed Echo Imaging System, 90 IYO
(per 21 CFR section 892.1560)

Manufacturer's Name: Shantou Institute of Ultrasonic Instruments

Address: #77, Jinsha Road,
Shantou SEZ, 515041, China

Corresponding Official: Li Delai

Title: President

Telephone: (86) 754-8250150 Fax: (86) 754-8251499

US Agent: Bob Leiker/ Consultant /QRS

7263 Cronin Circle, Dublin, CA 94568

Telephone: 1-925-556-1302 Fax: 1-866-718-3819

Predicate Device: SIUI CTS-485, K012772

Device Description:

The SIUI CTS-7700 is a digital diagnostic ultrasound system capable of the following operating modes: 2D (B mode) and B/M. The system is designed for use in linear and convex scanning modes and supports linear, and convex transducers. The system has cine review, image zoom, measurements and calculations, image storage and review, printing and recording capabilities. The system consists of probes, main unit, control panel and monitor.

Intended Use: Ultrasonic pulsed echo imaging and measurement for abdominal, pediatric, small organ, cardiac, peripheral vascular applications

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Technological Characteristics:

1) Scanning modes: convex and linear scanning
2) Display modes:
   a) B-Mode (B, 2B)
   b) B/M-Mode
3) Supporting transducers:
   a) C3L60B: 2.5-5.0 MHz 60R 128e convex transducer
   b) L7L38B: 5.0-9.0 MHz 38mm 128e linear transducer
4) Focus mode:
   a) Transmit focus mode: 1-4 selectable, focus depth: variable
   b) Receive focus mode: dynamic focus
5) Grey scale: 256
6) Pre-processing:
   a) 32-channel digital beam-former;
   b) Receive gain (include TGC): 70dB
   c) Dynamic range: 35-66dB
   d) Edge enhancement: 4 steps
   e) Image persistence: 7 steps
   f) Line density: normal, high
7) Post-processing
   10 types of gray maps, among which 4 types are user-definable
8) Image manipulation:
   a) Real-time zoom in x4.0 max.
   b) Frozen image
9) B/M-mode speed:
   Time for full screen scroll: 1.2, 2.5, 5.0, 10.0 sec
10) Cine: Max. 256 frames
11) Image store and recall: 32 frames
12) Image orientation:
   a) Left/right flip
   b) Up/down flip
   c) 90-degree rotation (selectable steps: 0, 90, 180, 270 degrees)
13) Documentation and storage:
   a) 60GB HDD, images stored in BMP file format;
   b) USB interface memory, images stored in BMP file format
   c) Documentation devices:
   d) B&W video printer
   e) Parallel port printer (Inkjet or LaserJet)
14) Measurements and calculations
   a) General measurements and calculations
      2D: Distance, Area, Circumference, and Angle
      M-Mode: Distance, Time, Slope, Heart rate
   b) Specific measurements and calculations

Abdomen, Obstetrics, Gynecology, Cardiology, Small parts, Peripheral Vascular

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Shantou Institute of Ultrasonic Instruments
% Mr. Bob Leiker
Consultant/QRS
7263 Cronin Circle
DUBLIN CA 94568

Re: K061083
Trade Name: CTS-7700 Digital Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: April 3, 2006
Received: April 18, 2006

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CTS-7700 Digital Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Convex Array C3L60B (2.5-5.0 MHz 60mm 128e convex transducer)
Linear Array L7L38B (5.0-9.0 MHz 38mm 128e linear transducer)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Sophie Paquerault at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

3.1 System Indications for Use Form

Device Name: CTS-7700

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal		N							N	
Abdominal		N							N	
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric		N							N	
Small Organ (Specify)		N							N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)		N							N	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		N							N	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)		N							N	

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Small organs include: thyroid, testes, breast Combined: B/M Mode

Other uses include: Uterus, Ovary, and Prostate

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061083

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.2 Transducer Indications for Use Form

Device Name: Convex Array C3L60B

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal		N							N	
Abdominal		N							N	
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)		N							N	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)		N							N	

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Uterus, Ovary, and Prostate, Combined: B/M Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061083

Prescription Use (Per 21 CFR 801.109)

K061083

SIUI CTS-7700 Digital Ultrasound Imaging System

Diagnostic Ultrasound Indications for Use Form

3.3 Transducer Indications for Use Form

Device Name: Linear Array L7L38B

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric		N							N	
Small Organ (Specify)		N							N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		N							N	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Small organs include: thyroid, testes, breast Combined: B/M Mode

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K061083

Prescription Use (Per 21 CFR 801.109)